K110954

510(k) SUMMARY
(as required by 807.92(c))

AUG 24 2012

Regulatory Correspondent:

Regulatory and Marketing Services, Inc.
962 Allegro Lane
Apollo Beach, FL 33572
Jonathan Ward
wardjp@ajwtech.com
813-645-2855
813-677-4787

Submitter of 510(k):

Arjo Wiggins Medical
1301 Charleston Regional Parkway, Suite 500
Charleston, SC 29492
Patrick Ritchie
PRitchie@arjomedical.com

Date of Summary: August 17, 2012

Trade/Proprietary Name: ArjoRad Sterilization Wrap

Classification Name: Sterilization Wrap

Product Code: FRG

Device Description:
ArjoRad Sterilization Wrap is a sterilization packaging system consisting of one SMS sheet to be double wrapped during use. ArjoRad Sterilization Wrap will be sold in a non-sterile condition in packaged form of various sizes depending on the needs of the end user.

Intended Use:
Used to enclose another medical device that is to be sterilized. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the device until used. ArjoRad Sterilization Wraps will maintain sterility for a maximum period of thirty (30) days. Intended for use with STERRAD 100S, NX, and 100NX Systems.

Sterilization Loads

Cycle	Recommended Instrument Configuration	Inside Diameter	Length	Recommended Individual Tray Load Weight	Number of Lumens per Validation Load	Cycle Length
STERRAD 100S	Stainless Steel Lumens	3 mm	400 mm	9.1 lbs	2 trays, 5 lumens each	55 minutes
STERRAD NX Standard	Single Channel PTFE Lumens	1 mm	150 mm	10.7 lbs	10 lumens	28 minutes
STERRAD NX Advanced	Single Channel Flexible Endoscope	1.2 mm	845 mm	10.7 lbs	1 endoscope	38 minutes
	Stainless Steel Lumens	1 mm	500 mm		10 lumens	
STERRAD 100NX Standard	Stainless Steel Lumens	0.7 mm	500 mm	10.7 lbs	2 trays, 5 lumens each	47 minutes
STERRAD 100 NX Flex	Single Channel Flexible Endoscope(s)	1.2 mm	830 mm	6.4 lbs	2 trays, 1 endoscope per tray	42 minutes
		1.2 mm	840 mm			
STERRAD 100 NX Express	Stainless Steel Surfaces (2mm x 8mm)	N/A	N/A	10.7 lbs	N/A	24 minutes

Predicate Device:
K092167 – Kimguard one step sterilization wrap – Kimberly – Clark Corporation

Substantial Equivalence:
The subject wraps have the same fundamental technological characteristics as the predicate device(s). Performance testing between the predicate device and the subject device have verified substantial equivalence in design, materials and intended use, and confirmed there are no significant differences between the proposed and predicate devices that raise new questions of safety or efficacy.

Performance Testing:
The intended use is to contain medical devices and to maintain sterility. Physical protection is consequently needed during the handling of non-sterile product. It is controlled with following performance testing: substance weight, strip tensile strength, Mullen burst and Elmendorf tear. Arjorad developed higher tensile strength and burst and tearing strength than predicate sterilization wrap. In addition ArjoRad meets the acceptance criteria with regard to the minimum requirement for strength properties dedicated to non-woven sterilization wrap. When applied to the minimum performance level, the properties of ArjoRad still meet the criteria of acceptation after sterilization which equals the minimum requirement level for sterilization wrap defined according to EN 868-2:2009 and ASTM D737: Standard Test Method for Air Permeability of Textile Fabrics.

During microbial aerosol challenge test, similarly to predicate, ArjoRad demonstrated germ resistance after hydrogen peroxide sterilization cycle. The microbial aerosol challenge test and the shelf life study demonstrate that, the subject wrap is considered as a sterile barrier system that is capable to maintaining sterility for 30 days after sterilization, as long as the sterile barrier is not compromised in any way.

The ability to let the sterilant penetrate has been validated as well. This was demonstrated by sterilization efficacy studies after different cycles of STERRAD hydrogen peroxide gas plasma sterilization. Studies carried out demonstrated that Arjorad can assure an SAL of 10^{-6} after each half cycle tested.

Conclusion: The minor differences between the proposed and predicate devices do not introduce new issues of safety and efficacy. The ArjoRad Sterilization Wrap is substantially equivalent to the predicates in that it meets all of the requirements for use in a STERRAD 100S, NX and 100NX Systems. All testing performed indicates that the ArjoRad Sterilization Wrap will provide a sterile barrier for use in the STERRAD device. There are a series of detailed Comparison Tables for testing results included in Section 18 Performance Testing, which was completed by comparing the ArjoRad Sterilization Wrap against the primary predicate device. The KC300 sterilization wrap chosen as a test predicate has been cleared for low temperature V-Pro sterilization, the comparative performance data demonstrates that the proposed device performs equally or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Arjo Wiggins Medical, Incorporated
C/O Mr. Jonathan Ward
President
Regulatory and Marketing Services, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

AUG 24 2012

Re: K110954
Trade/Device Name: ArjoRad Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: August 17, 2012
Received: August 22, 2012

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110954

Indications for Use

510(k) Number (if known): K110954

Device Name: ArjoRad Sterilization Wrap

Used to enclose another medical device that is to be sterilized. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the device until used. ArjoRad Sterilization Wraps will maintain sterility for a maximum period of thirty (30) days. Intended for use with STERRAD 100S, NX, and 100NX Systems

Sterilization Loads

Cycle	Recommended Instrument Configuration	Inside Diameter	Length	Recommended Individual Tray Load Weight	Number of Lumens per Validation Load	Cycle Length
STERRAD 100S	Stainless Steel Lumens	3 mm	400 mm	9.1 lbs	2 trays, 5 lumens each	55 minutes
STERRAD NX Standard	Single Channel PTFE Lumens	1 mm	150 mm	10.7 lbs	10 lumens	28 minutes
STERRAD NX Advanced	Single Channel Flexible Endoscope	1.2 mm	845 mm	10.7 lbs	1 endoscope	38 minutes
	Stainless Steel Lumens	1 mm	500 mm		10 lumens	
STERRAD 100NX Standard	Stainless Steel Lumens	0.7 mm	500 mm	10.7 lbs	2 trays, 5 lumens each	47 minutes
STERRAD 100 NX Flex	Single Channel Flexible Endoscope(s)	1.2 mm	830 mm	6.4 lbs	2 trays, 1 endoscope per tray	42 minutes
		1.2 mm	840 mm			
STERRAD 100 NX Express	Stainless Steel Surfaces (2mm x 8mm)	N/A	N/A	10.7 lbs	N/A	24 minutes

Prescription Use (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110954